DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Evaluation of Dietary Protein Intake Requirements

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Evaluation of Dietary Protein Intake Requirements,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES:

E-mail submissions: epc@ahrq.hhs.gov

Print submissions:

Mailing Address:

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

5600 Fishers Lane

Mail Stop 06E53A

Rockville, MD 20857

Shipping Address (FedEx, UPS, etc.):

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

5600 Fishers Lane

Mail Stop 06E53A

Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT:

Kelly Carper, Telephone: 301-427-1656 or Email: epc@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Evaluation of Dietary Protein Intake Requirements.* AHRQ is conducting this systematic review pursuant to section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on Evaluation of Dietary Protein Intake Requirements*,* including those that describe adverse events. The entire research protocol is available online at: https://effectivehealthcare.ahrq.gov/products/dietary-protein-intake/protocol.

This is to notify the public that the EPC Program would find the following information on Evaluation of Dietary Protein Intake Requirements helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number*.

        - *For completed studies that do not have results on ClinicalTrials.gov*, a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.
    - *A list of ongoing studies that your organization has sponsored for this indication*. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
    - Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: https://www.effectivehealthcare.ahrq.gov/email-updates.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

KQ 1: What is the average daily dietary protein intake requirements of apparently healthy individuals by life stage and sex?
KQ 2: What is the average daily dietary individual indispensable amino acid intake requirements of apparently healthy individuals by life stage and sex?

Population, Intervention, Comparator, Outcome, Timing, Setting/Study Design (PICOTS)

Element	Inclusion Criteria	Exclusion Criteria
Population KQ1 & 2	● Participants who are healthy and/or have chronic diseases or chronic disease risk factors, including those with obesity ● Studies that enroll some participants diagnosed with a disease or hospitalized or in a long-term care facility with an illness or injury ● Studies that enroll some participants diagnosed with a disease or with the health outcome of interest ● Participants who are pregnant and lactating ● Age at intervention exposure: ○ Infants, children, adolescents (0-18 years) ○ Adults (19-64) ○ Older adults (65 years and older)	● Studies that exclusively enroll participants diagnosed with a disease, hospitalized, or in a long-term care facility with an illness or injury (for this criterion, studies that exclusively enroll participants with obesity will not be excluded) ● Studies that aim to treat participants who have already been diagnosed with the outcome of interest (except weight loss interventions in overweight or obese subjects) ● Studies that exclusively enroll undernourished participants ● Studies that exclusively enroll participants with a baseline diet deficient in protein ● Studies that exclusively enroll preterm infants ● Studies that exclusively enroll post-bariatric surgery subjects ● Studies that exclusively recruit elite athletes ● Participants with existing conditions that clearly are known to alter nutrient metabolism or requirements, or those being treated with medications that alter

		nutrient metabolism
Interventions KQ1 & 2	• Total daily protein intake level • Total daily intake of indispensable AAs (Histidine, Isoleucine, Leucine, Lysine, Methionine, Phenylalanine, Threonine, Tryptophan, Valine)	• Studies that **only** assess protein intake via infusions (rather than the GI tract) • Studies that examine food products or dietary supplements not widely available to U.S. consumers • Multi-component interventions that do not isolate the effect or association of protein (including protein and exercise combinations)
Comparison KQ1 & 2	• Different total daily protein intake level • Different total daily intake of indispensable AAs	• No comparator
Outcomes KQ1	Total protein requirement* as defined by the following indicators or criterion of adequacy, including but not limited to: • Nitrogen balance method • Factorial method • Indicator AA oxidation method • Mean protein intake of infants fed principally human milk (0-6 months) • Mean protein content of human milk (0-6 months) • Body composition (lean mass) • Linear growth for infants, children, adolescents (0-18 years) • Activities of daily living for older adults (65 years and older)	
Outcomes KQ2	Indispensable AA requirement* as defined by the following indicators of adequacy, including but not limited to: • Plasma AA response method • Direct AA oxidation	

	method ● 24-hour AA balance method ● Indicator AA oxidation method ● Mean AA intake of infants fed principally human milk (0-6 months) ● Mean protein content of human milk (0-6 months)	
Timing KQ1 & 2	● All duration and follow up	
Setting KQ1 & 2	● All settings	
Study Design KQ1 & 2	● Randomized controlled trials ● Non-randomized controlled trials, including quasi-experimental and controlled before-and-after studies ● Prospective cohort studies ● Nested case-control studies	● International and government reports ● Narrative reviews ● Systematic reviews, meta-analyses, umbrella reviews, scoping reviews ● Uncontrolled trials ● Case-control studies ● Uncontrolled before-and-after studies ● Retrospective cohort studies
Study Size KQ1 & 2		● N < 6 participants and without power for crossover studies ● Other studies with N < 50 participants (for RCTs - 25 participants analyzed per study arm), and without power calculations
Language KQ1 & 2	● English only (due to resource limitations)	
Geographic Location KQ1 & 2	● Locations with food products or dietary supplements widely available to U.S. consumers, including those rated very high on the Human Development Index	

Publication Date KQ1 & 2	• 2000 to present	
Publication Status KQ1 & 2	• Articles published in peer-reviewed journals	• Articles that have not been peer reviewed and are not published in peer-reviewed journals (e.g., unpublished data, manuscripts, pre-prints, reports, abstracts, conference proceedings)

*Requirement is defined as the lowest daily intake value for a nutrient that will meet the need as defined by a specified indicator or criterion of adequacy, of apparently healthy individuals

Dated: June 8, 2023.

Marquita Cullom,

Associate Director.

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